

### Remarks

Claims 1-26, 31-40, 44 and 45 are pending in the application and subject to restriction. Restriction has been required from among four groups of claims identified as follows:

I. Claims 1-25, characterized as drawn to a method of producing a soluble bioactive domain of a protein;

II. Claims 31-34, characterized as drawn to expression constructs for the production of recombinant polypeptides with sortase gene product as a purification tag;

III. Claims 35-39, characterized as drawn to a method of producing a polypeptide and a fusion polypeptide obtained by the method;

IV. Claim 40, characterized as drawn to a purification tag comprising a sortase gene product; and

V. Claims 26, 44 and 45, characterized as drawn to a method for producing a soluble bioactive domain of a protein comprising a solubility enhancing tag comprising a SNUT tag.

### Election

Applicants elect the claims of Group V, constituting claims 26, 44 and 45. The election is made with traverse, for the reasons set forth below. Applicants reserve the right to request rejoinder of any non-elected claim pursuant to MPEP 821.04.

### Traversal of Restriction

Applicants respectfully traverse the finding of lack of unity as it applies to Groups II, III, IV and V. Examiner alleges that the claims of the application do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they allegedly lack the same or corresponding technical feature. Examiner alleges that Zhang *et al.*, Pryor *et al.*, Ton-That *et al.* (described in the office action as “Hung *et al.*”), and Ilangovan *et al.* (described in the office action as “Udayar *et al.*”) each disclose “a method of producing a soluble bioactive domain of a protein”, thereby allegedly teaching a technical feature linking the claims. Applicants respectfully disagree.

The technical feature linking the claims of Groups II-V is the use of a Sortase gene product as a purification tag. The Group II claims (claims 31-34) are directed to expression constructs for the production of the recombinant polypeptides in which a Sortase gene product is used as a purification tag sequence. As clearly taught by the specification, the SNUT tag (present in claims 44 and 45) is a tag derived from a Sortase gene product (see, for example, page 6, lines 24-26 of the application as filed). As the expression constructs of claims 31-34 comprise a coding region encoding a Sortase gene product as a purification tag sequence, they share the same technical feature as the claims of Group V (claims 26, 44 and 45), *i.e.*, the use of a Sortase gene product as a solubility enhancing purification tag

None of the cited documents make any reference to Sortase gene products as purification tags. Thus, the common technical feature linking Groups II and V under the terms of PCT Rule 13.1 and PCT Rule 13.2, is novel.

Zhang *et al.* describes the fusion of various proteins to a mutant form of DsbA with no mention of the use of Sortase as a purification tag.

Pryor *et al.* describes expression of soluble protein using a His<sub>6</sub>-tag and Maltose-binding-protein double affinity fusion system with no mention whatsoever of the use of a Sortase gene product.

Ton-That *et al.* describes the purification and characterization of Sortase and its use to catalyze surface-protein anchoring. There is no disclosure whatsoever in this document of the use of Sortase as a purification tag or indeed any indication from this document that Sortase could be used for such a purpose.

Ilangovan *et al.* also relates to Sortase and its characterization. The document concentrates in the properties of Sortase in cleaving LPXTG peptides. As with Ton-That *et al.*, no teaching or suggestion whatsoever is made by Ilangovan *et al.* with respect to the use of Sortases as purification tags, as taught by applicants.

The claims of claim Group III (claims 35-39) further share the special technical feature of Groups II and V, *i.e.*, the use of a Sortase gene product as a purification tag. The main claim of this group, claim 35, recites a method of producing a polypeptide that utilizes in step (b) thereof ***an expression construct as claimed in claim 31, i.e.***, an expression construct that comprise a

coding region encoding a Sortase gene product as a purification tag sequence. The expression construct is utilized in the preparation of an expression vector, which is in turn used to transform host cells to produce fusion polypeptide comprising the encoded Sortase gene product as a purification tag. Thus, the special technical feature shared by Groups II and V — the use of a Sortase gene product as a purification tag — is also a technical feature shared by Group III.

The claim of Group IV (claim 40) also shares the same special technical feature that is in common with Groups II, III and V. Claim 40 recites a purification tag that comprised a specific sortase gene product comprising amino acids 13-157 of SEQ ID NO:5, or a variant or fragment thereof.

None of the documents upon which the Examiner bases the lack of unity objection makes any reference to purification tags comprising Sortase gene products, or the use of Sortase gene products as purification tags. Thus, the common technical feature linking Groups II-V is novel, and comprises a special technical feature under PCT Rule 13.1 and PCT Rule 13.2. Accordingly, the Examiner is respectfully requested to reconsider the finding of lack of unity, at least insofar as it relates to the claims of Groups II, III, IV and V.

Remarks Regarding Species Election Requirement

An election of species has been required, but only if Group I is elected. Since Group I is not elected, no election of species is required.

Respectfully submitted,

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